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Facsimile

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To	Firm Name	Phone	Fax
Commissioner for Patents	United States Patent and Trademark Office; Office of Petitions		703-308-6916

From:

Daniel S. Kasten

Date:

11/04/2003

Message:

Application of: Wold et al. Serial No: 09/111,911

Filed: July 8, 1998

Title: Inhibiting Apoptosis with Adenovirus RID Protein

Examiner: Ram R. Shukla, Ph.D.

Group Art Unit: 1632

Petition to Commissioner under 37 CFR 1.181

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PETITIONS OFFICE

Atty/Client/Matter No.:

3067/66153/05587

Total Number of Pages, including this page:

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Fax Department - Operator;

Time of Transmittal: 7/5 A.M./P.M.

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PTO/SB/17 (11-00) Approved for ties through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Onder the Paperwork Rossessian	Complete if Known							
FEE TRANSMITTAL	Application Number 09/111,911							
	Application Number 09/11,911 Filing Date July 8, 1998							
for FY 2001	First Named Inventor Wold, William S.M.							
	Pam P Shukla Ph D							
Patent fees are subject to annual revision.	Group Art Unit 1632							
TOTAL AMOUNT OF PAYMENT (\$)130	Group Art Unit 1632 Attorney Docket No. 66153-5587							
METHOD OF PAYMENT	FEE CALCULATION (continued)							
The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:	3. ADDITIONAL FEES Large Small Entity Entity Entity							
Deposit Account Number	Fee Fee Fee Fee Fee Fee Fee Fee Paid Code (8) Code (3) Fee Description Fee Paid 105 130 205 65 Surcharge - late high red diches OFFICE							
Deposit Account	127 50 227 25 Surcharge – late provisional filing tee or cover sheet							
Name	139 130 139 130 Non-English specification							
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Applicant claims amail entity status.	112 920° 112 920° Requesting publication of SIR prior to Examinar action							
See 37 CFR 1.27 2. Payment Enclosed: Money Clother	113 1,840° 113 1,840° Requesting publication of SIR after Examiner action							
Check Credit Card Order Other	115 110 216 55 Extension for raply within first month							
FEE CALCULATION	118 400 216 200 Extension for reply within second month							
1. BASIC FILING FEE	117 920 217 460 Extension for reply within third month 118 1,440 216 720 Extension for reply within fourth month							
Large Entity Small Entity	118 1,440 218 720 Extension for reply within fourth month 128 1,980 228 980 Extension for reply within fifth month							
Fee Fee Fee Fee Fee Description Gode (6) Code (5)	118 320 219 160 Notice of Appeal							
101 740 201 370 Utility filing fee	120 320 220 160 Filling a brief in support of an appeal							
108 330 206 165 Design filling fee	121 280 221 140 Request for oral hearing							
107 510 207 255 Plant thing fee	138 1,510 138 1,510 Petition to institute a public use proceeding							

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110 240 Petition to revive - unavoidable

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				141 (4)	141	1,280	241	640	Petition to revive - unintentional
				SUBTOTAL (1) (\$)	142	1,280	242	640	Utility issue fee (or release)
2. EXT	RA C	LAIM	FEE:	•	143	460	243	230	Design lasus fee
				Fee from	144	620	244	310	Plant issue fee
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Independent	} =	===	-3~ =		123	SQ	123	50	Processing fee under 37 CFR 1.17(q)
-			~ -,		126	180	126	180	Submission of Information Disclosure Stmi
Multiple Depr	engent Entity	Small	Entity		581	40	581	40	Recording each patent assignment per property (times number of properties)
Fes Code	Feet (\$)	Fee Code	Fee (\$)	Fee Description	146	740	246	370	Filing a submission after final rejection (37 CFR § 1.129(s))
103 102	18 84	203 202	9 42	Claims in excess of 20 independent claims in excess of 3	149	740	249	370	For each additional invention to be examined (37 CFR § 1,129(b))
104	280	204	140	Multiple dependent claim, if not paid	179	740	279	370	Request for Continued Examination (RCE)
109	84	209	42	** Reissus Independent claima over original patent	168	900	169	900	Request for expedited exemination of a design application
110	18	210	9	** Relatue claims in excess of 20 and over original patent	Other fo	e (specify)		
				SUBTOTAL (2) (\$)	*Reduc	ed by Ba	sic Fill	ng Fee P	aid SUBTOTAL (3)

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Provisional fillna fee

or number previously paid, if graster, For Reissues, see above SUBMITTED BY Complete (if applicable) Registration No. (Attorney/Agent) Name (Print/Type) Daniel S. Kasten 45,363 Telephone 314-552-6305 November 4, 2003 Signature

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PTO/SB/17 (11-00)

Approved for use through 10/31/2002. OMB 0651-0032 U.S. Petent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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FEE TRANSMITTAL for FY 2001

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT (\$)130

Complete if Known					
Application Number	09/111,911				
Filing Date	July 8, 1998				
First Named Inventor	Wold, William S.M. R. Z				
Examiner Name	Ram R. Shukla, Ph.D.				
Group Art Unit	1632				
Attorney Docket No.	66153-5587				

METHOD OF PAYMENT			F	EE C	ALCULATION COMMING CETT S
The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:	3. A	Large	IONAI	Small	NOV 0 4 2003
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Deposit Account Name	127	50	227	25	Surcharge – late provisional filling fee or cover sheet
Charge Any Additional Fee Required	139	130	139	130	Non-English apacification
Under 37 CFR 1.16 and 1.17.	147	2,520	147	2,520	For filling a request for ex parts reexemination
Applicant claims small entity status. See 37 CFR 1.27	112	920*	112	920*	Requesting publication of SIR prior to Examiner action
2. Payment Enclosed:	113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action
☐ Check ☐ Credit Card ☐ Norder ☐ Other	115	110	215	55	Extension for reply within first month
FEE CALCULATION	116	400	216	200	Extension for reply within second month
	117	920	217	480	Extension for raply within third month
1. BASIC FILING FEE	118	1,440	218	720	Extension for reply within fourth month
Large Entity Small Entity Fee Fee Fee Fee Description	128	1,960	228	980	Extension for reply within fifth month
Code (\$) Code (\$) Fee Paid 101 740 201 370 Utility filing fee	119	320	219	160	Notice of Appeal
101 740 201 370 Utility filing fee 106 330 206 165 Design filing fee	120	320	220	160	Filling a brief in support of an appeal
107 510 207 255 Plant filling fee	121	280	221	140	Request for oral hearing
10a 740 208 370 Reissue filing fee	138	1,510	138	1,510	Petition to institute a public use proceeding
114 180 214 80 Provisional filing fee	140	110	240	55	Potition to revive - unavoidable
SUBTOTAL (1) (5)	141	1.280	241	640	Petition to revive unintentional
	142	7,280	242	640	Utility issue fee (or reissue)
2. EXTRA CLAIM FEES	143	460	243	230	Design lasue fee
Extra Claims Fee from	144	620	244	310	Plant issue fee
Total Claims -20** = X =	122	130	122	130	Petitions to the Commissioner 130
Independent 3**= X =	123	50	123	50	Processing fee under 37 CFR 1.17(q)
Multiple Dependent	126	180	126	180	Submission of Information Disclosure Stmt
Large Entity Small Entity	581	40	581	40	Recording each patent assignment per property (times number of properties)
Fee Fee Fee Fee Description Code (\$) Code (\$) 103 18 203 9 Claims in except of 20	146	740	246	370	Filling a submission after final rejection (37 CFR § 1.129(a))
102 84 202 42 Independent claims in excess of 3	149	740	249	370	For each additional invention to be
104 280 204 140 Multiple dependent claim, if not paid	179	740	279	370	exemined (37 CFR § 1.129(b)) Request for Continued Examination (RCE)
109 84 209 42 ** Reissue Independent claims over original patent	169	900	169	900	Request for expedited examination (RCE) Request for expedited examination of a design application
110 18 210 9 Relasue cialma in excess of 20 and over original patent	Other fee	o (specify)		
SUBTOTAL (2) (\$)	*Reduç	ed by Ba	asic Filing	Fee P	aid SUBTOTAL (3) (\$) 130

SUBMITTED BY				Complete (if	applicable)
Name (Print/Type)	Daniel S. Kasten	Registration No. (Attomey/Agent)	45,363	Telephone	314-552-6305
Signature	David & Than	T		Date	November 4, 2003

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TECHCHIER TOO TOO TOO I hereby certify that the foregoing document and all referenced attachments were transmitted via facsimile to the Office of Petitions at the U.S. Patent and Trademark Office, facsimile number 703-308-6916, on November 4, 2003.

> Daniel S. Kasten Registration No. 45,363

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Wold, William S.M.

Group No.:

1632

Serial No.:

09/111.911

Atty. Docket No.:

66153-5587

Filed:

July 8, 1998

For:

INHIBITING APOPTOSIS WITH ADENOVIRUS RID Examiner:

Ram R. Shukla, Ph.D.

PROTEIN

Office of Petitions Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

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PETITIONS OFFICE

PETITION UNDER 37 C.F.R. § 1.181

Applicant hereby petitions the commissioner, under 37 C.F.R. §1.181 for reconsideration of the Examiner's decision not to enter Applicant's amendment (dated October 4, 2002) and response after advisory action. Applicant requests that the amendment be entered and the claims be allowed. The facts are as follows:

In a final Office Action dated June 17, 2002 (copy enclosed), the Examiner indicated that of the pending claims (1, 4, 7, 10, 13 and 23-26), claims 1, 4, and 23-26 are allowed; claims 7, 10 and 13 are rejected; and claim 26 is objected to, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant filed a response to the final Office Action on August 14, 2003 (copy enclosed), in which claim 7 was canceled, and new claims 27 and 28 were added. Arguments were submitted in support of the pending claims.

The Examiner issued an Advisory Action on September 13, 2002 indicating that Applicant's amendment of August 14, 2002 had not been entered and again indicating that claims 1, 4, 7, 10, 13 and 23-26 are pending; claims 1, 4 and 23-25 are allowed; claim 26 is objected to; and claims 7, 10 and 13 are rejected.

Applicant then filed, on October 4, 2002, an amendment (copy enclosed) in which claims 7, 10 and 13 are canceled; and claim 26 is amended to be in independent form, incorporating all of the limitations of the base claim and all intervening claims, as required. That response was received by the USPTO, as indicated in the enclosed Auto-Reply Facsimile Transmission. However, for reasons unclear to Applicant, the response was not married up to the file once received by the USPTO. Applicant subsequently re-submitted the response on April 3, 2003, and again on June 3, 2003, at which point it finally was matched up with the file, and forwarded to the Examiner.

The Examiner then issued a second Advisory Action, dated September 4, 2003, indicating that the amendment filed on October 4, 2002 was not entered, and again indicating that claims 1, 4, 7, 10, 13 and 23-26 are pending; claims 1, 4 and 23-25 are allowed; claim 26 is objected to; and claims 7, 10 and 13 are rejected. The Examiner asserts that the Response of October 4, 2002 does not address the enablement rejection relative to claim 26, as amended. Applicant points out that claim 26 was never rejected on the grounds of enablement, and as indicated in the final Office Action, and subsequent Advisory Actions, is allowable if amended to be in independent form.

The Examiner further asserts that Applicant does not address the status of claims 27 and 28 in the Response of October 4, 2002. Here, Applicant points out that those claims were added by an amendment, filed August 14, 2002, that was not entered. Thus, those claims were never pending. Further, the Advisory Actions of 9/13/02 and 9/4/03 indicate that claims 27 and 28 are NOT pending.

The Examiner further asserts that Applicant did not provide any new arguments as to how the proposed amendment to claim 26 addressed the enablement rejection set for in the previous Office Actions. Again, Applicant points out that claim 26 was NOT subject to an enablement rejection, and thus argument to overcome that rejection is not necessary. As previously discussed, the Examiner had previously indicated that claim 26 is allowable, if rewritten in independent form, incorporating all of the limitations of the base claim and intervening claims. Applicant has done so.

In summary, Applicant hereby asserts that all of the outstanding issues are obviated by Applicant's response filed October 4, 2002, and thus the Examiner has improperly refused to enter that amendment and allow the case to proceed to issuance. According to 37 C.F.R. §1.116(b), "After a final rejection or other final action (§1.113) in an application..., amendments

may be made canceling claims or complying with any requirement of form expressly set forth in a previous Office action." Here, Applicant's Response of October 4, 2002 merely cancels rejected claims, and amends claim 26 in compliance with the requirement expressly set forth in the Final Office Action of June 17, 2002. Thus, the Response complies with 37 C.F.R. §1.116, and therefore the Examiner improperly refused entry. Claims 27 and 28 were never entered, and thus need not be addressed. However, to the extent necessary, Applicant hereby authorizes and directs the Office to withdraw and/or cancel claims 27 and 28. Since the only claims remaining after entry of the amendment of October 4, 2002 are, as indicated by the Examiner, allowable, Applicant hereby requests that the Examiner's refusal to enter the Response of October 4, 2002 be withdrawn, that the Response of October 4, 2002 be entered, and that the case proceed to allowance.

Respectfully submitted,

Daniel S. Kasten, Reg. #45363

Thompson Coburn LLP One US Bank Plaza

St. Louis, Missouri 63101

Telephone: 314-552-6305

Fax: 314-552-7305



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARK Washington, D.C. 20331

	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
	09/111,911	1,911 07/08/1998 WILLIAM S. M. WOLD		16153-5587	6287	
•	21888	7590 06/17/2002				
	THOMPSON ONE FIRSTA	N COBURN, LLP		EXAMI	NER	
	SUITE 3500		•	SHUKLA,	RAM R	
	ST LOUIS, M	IO 63101		ART UNIT	PAPER NUMBER	
				1632	10	
				DATE MAILED; 06/17/2002	10	

Please find below and/or attached an Office communication concerning this application or proceeding.

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JUN 2 4 2002

Thompson Coburn LLP

Advisory due 8/19/02 Appendue KETED/TC Ite: 9/19/02: 12/19/03

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PTO-90C (Rov. 07-01)

		Application No.	Applicant(s)					
		09/111,911	WOLD, WILLIAM S. M.					
	Office Action Summary	Examiner	Art Unit					
		Ram Shukla	1632					
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	correspondence address					
THE - External control	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication, a period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period vire to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37, CFR 1,704(b),	38(a). In no event, however, may a reply be ting within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed 's will be considered timely. I the mailing date of this communication. D (35 U.S.C. § 133).					
1)⊠	Responsive to communication(s) filed on 02 A	April 2002 .						
2a)⊠	This action is FINAL. 2b) Th	is action is non-final.						
3)	<u></u>							
Disposit	ion of Claims	, , , , , , , , , , , , , , , , , , , ,						
4)⊠	Claim(s) <u>1.4.7.10.13 and 23-26</u> is/are pending	in the application.						
14	4a) Of the above claim(s) is/are withdray	· •						
1	Claim(s) 1.4 and 23-25 is/are allowed.		e .					
1	Claim(s) 7.10 and 13 is/are rejected.		FAX RECEIVED					
	Claim(s) <u>26</u> is/are objected to.		NOV 0 4 2003					
1	Claim(s) are subject to restriction and/or	election requirement	1404 O 4 5003					
	Application Papers PETITIONS OFFICE							
9)□ .	The specification is objected to by the Examiner							
4	The drawing(s) filed on is/are; a)☐ accept		niner					
	Applicant may not request that any objection to the	drawing(s) be held in abevance. Se	ne 37 CFR 1 85/a)					
11)		is: a) approved b) disapprov						
	If approved, corrected drawings are required in repl	y to this Office action.	A					
12) 🔲 🗆	The oath or declaration is objected to by the Exa	miner.						
Priority u	nder 35 U.S.C. §§ 119 and 120		E & C					
13)	Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. & 119(a)	-(d) or (d)					
a)[☐ All b)☐ Some * c)☐ None of:	, , , , , , , , , , , , , , , , , , , ,	12 -					
	1. Certified copies of the priority documents	have been received	75 003					
	2. Certified copies of the priority documents have been received in Application No.							
If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.								
14) 🗌 Ad	cknowledgment is made of a claim for domestic	priority under 35 U.S.C. & 119(e)	/to a provisional application					
(a)	☐ The translation of the foreign language provices in the provice of a claim for domestic made of a claim for domestic.	Sional application has been recei	vad					
	of References Cited (PTO-892)	٠. ١						
2) Notice 3) Informa	of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s)	E\	PTO-413) Paper No(s) ient Application (PTO-152)					
U.S. Patent and Trac PTO-326 (Rev.	lemark Office 04-01) Office Actio	n Summary	Sort of Danot No. 10					

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Page 2

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DETAILED ACTION

- The request filed on 4-2-02 for a Continued Prosecution Application (CPA) 1. under 37 CFR 1.53(d) based on parent Application No. 09/111,911 is acceptable and a CPA has been established. An action on the CPA follows. It is noted that the applicants had filed an RCE under 37 CFR 1.114, however, the request was treated as a request for CPA as noted in the communication of 5-28-02, since the parent application was filed prior to 29 May 2000 and this was the first instance of continuation application filing,
- Amendment/response filed 4-2-02 is acknowledged. 2.
- 3. Claim 14 has been cancelled.
- 4. New claims 26 has been entered.

Application/Control Number: 09/111,911

Art Unit: 1632

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5. Amendments to claims 4, 7, 10 and 13 have been entered.

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4. Claims 1, 4, 7, 10, 13 and 23-26 are pending.

PETITIONS OFFICE

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112: 6.

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 13 remain rejected and the amended claim 7 are rejected under 7. 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an in vitro method of inhibiting apoptosis of a cell, wherein the cell expresses Fas, TNFR-1, DR-3, TRAIL-R1, or TRAIL-2, comprising, contacting the cell with an adenovirus comprising a CMV promoter operably linked to a polynucleotide that encodes a RIDa polypeptide, a RIDa-L, and a RIDp, disclosed in SEQ ID NO:1, SEQ ID NO: 2, and SEQ ID NO:4, wherein the adenovirus enters the cell, the RIDa polypeptide, a RIDcc-L, and a RIDp are expressed in the cell in an amount sufficient to inhibit apoptosis of the cell, the adenovirus lacks at least one functional E1 gene, the cell expresses Fas, DR3, TRAIL-R1, or TRAIL-R2, and the apoptosis is mediated

Page 3

Application/Control Number: 09/111,911

Art Unit: 1632

by Fas receptor activity, does not reasonably provide enablement for other embodiments for reasons of record set forth in the previous office action of 10-15-01 and 1-2-02.

It is noted that applicants have not presented any new arguments regarding the grounds of rejection set forth in the previous office action of 10-15-01 and 1-2-02. They have rather asserted that the claim 10 as amended does not rely on the fact that the murine model presented in example 9 is an art recognized model. Applicants further argue that example 9 describes transplantation of heterologous cells into an immunocompetent animal which were able to grow in the animal. While the claim 10 as amended recites a method of decreasing the rejection of transplanted cells compared to previously recited method of decreasing the rejection of cells in a patient, the amendment does not obviate the rejection set forth in the previous office actions of 1-2-02 since the method is interpreted as a method of treatment wherein cells are transplanted in a patient, the rejection of the cells is decreased, and the cells treat the disease such as degenerative disease or an immunodeficiency disease. As noted in the previous office action of 10-15-01, the specification is not enabling for the claimed invention because the mouse model disclosed in the specification is not an art recognized model of cell or tissue transplantation and rejection.\Regarding claim 7, it is noted that as amended it depends from claim 4 which in turn depends from claim 1. While claim 1 is enabled, claim 7 is not enabled since its utility as recited in the claim is for transplantation in a patient, which is not enabled as discussed.

- 8. Claims 1, 4 and 23-25 are free of the prior art of record.
- 9. Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See

Application/Control Number: 09/111,911

Art Unit: 1632

MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filled within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If the claims are amended, added and/or canceled in response to this office action the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (http://www.uspto.gov) and a clean copy of all pending claims is requested.

Any Inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (703) 305-3388.

Ram R. Shukla, Ph.D.

RAM R. SHUKLA, PH.D. PATENT EXAMINER Page 4

☐ Fee Catalators ☐ Notice of Appeal ☐ Appeal Brief ☐ Statisment Under 3.73 (b) ☐ Other
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		ey Docket M		66153-5587			First Inventor: Wold, William S.M.			1 S.M.			
	AMENDMENT TRANSMITTAL LETTER						Serial I	Vo		09/1	11,911		
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF MAILING UNDER 37 CFR §1.8

I hereby certify that this correspondence and documents referred to as enclosed therein are being deposited with the United States Postal Service with sufficient postage as first class day of Augus + , 2002 in an envelope addressed to: BOX 14 Hz NONFEE AMENDMENT, Assistant Commissioner for Patents, Washington, D.C. 20231.

Application of:

Wold, William S. M. Group No.:

1632

Serial No.:

09/111.911

Atty. Docket No.:

66153-5587

Filed:

July 8, 1998

For:

Inhibiting Apoptosis with

Examiner:

Shukla, Ram R.

Adenovirus RID Protein

Commissioner of Patents and Trademarks

Washington, DC 20231

AMENDMENT AND RESPONSE

HONORABLE SIR:

Applicant submits this paper in response to the Office Action, paper no. 19, mailed on June 17, 2002, and in accordance with Rule 1.111 of the Rules of Practice. Applicants respectfully requests reconsideration and entry of the following amendments and remarks intended to put the above-identified application into form for allowance.

Application Serial No. 09/111,911

IN THE CLAIMS:

Please cancel claim 7.

Claims 10 and 26 have been amended as indicated in a marked-up version of the claims attached hereto:

10. (Five times amended) A method for inhibiting apoptosis in a cell comprising contacting the cell with a recombinant adenovirus comprising a polynucleotide encoding a RIDα-S polypeptide, a RIDα-L polypeptide and a RIDβ polypeptide, as disclosed in SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:4, wherein (a) the polynucleotide is operably linked to a cytomegalovirus ("CMV") promoter, (b) the adenovirus enters the cell and delivers the polynucleotide to the cell, (c) the RIDα-S polypeptide, RIDα-L polypeptide and RIDβ polypeptide are expressed in the cell in an amount sufficient to inhibit apoptosis of the cell, (d) the cell expresses Fas, DR3, TRAIL-R1, or TRAIL-R2, and (e) the adenovirus lacks at least one functional E1 gene and, wherein said cell is introduced into a host.

26. (Amended) The method of claim 13 wherein the host is a mouse.

Please add the following new claims:

- 27. (New) The method of claim 10, wherein the cell is a human cell.
- 28. (New) The method of claim 27, wherein the cell is an A549 cell.

REMARKS

Claims 1, 4, 7, 10, 13, and 23-26 are pending in the instant application. Claims 10 and 26 have been amended. Claims 27 and 28 have been added. Claim 7 has been cancelled.

Application Serial No. 09/111,911

Claims 1, 4, and 23-25 are allowed. Claim 26 is objected to. Claims 7, 10, and 13 stand rejected under 35 U.S.C. § 112, first paragraph, for an alleged failure to provide an enabling description. Specifically, the Examiner alleges that:

[T]he specification, while being enabling for an in vitro method of inhibiting apoptosis of a cell, ...does not reasonably provide enablement for other embodiments for the reasons of record....

While the claim 10 as amended recites a method of decreasing the rejection of transplanted cells compared to previously recited method of decreasing the rejection of cells in a patient, the amendment does not obviate the rejection set forth in the previous office action of 1-2-02 since the method is interpreted as a method of treatment wherein cells are transplanted in a patient, the rejection of the cells is decreased, and the cells treat the disease such as degenerative disease or an immunodeficiency disease....[T]he specification is not enabling for the claimed invention because the mouse model disclosed in the specification is not an art recognized model of cell or tissue transplantation and rejection.

Claim 7 has been cancelled. Although Applicant believes that the specification fully enables a method of decreasing rejection of transplanted cells, solely to advance the prosecution of the instant application, Applicant has amended claim 10 to recite a method of inhibiting apoptosis, which is consistent with the allowed claims. Applicant has also added claims 27 and 28. Support can be found in Examples 7-9. Specifically, cells introduced into an immunocompetent host are usually destroyed by immune killer cells of the host. Examples 7 and 8 show that the RID complex can inhibit apoptosis. Example 9 describes introduction of the 231-10 vector (described on p. 5, lines 25-29 and p. 28, lines 5-11 as having the RID complex) into a human cancer cell line, such as A549. The cell is then introduced into a murine host. While a small mass grew in the mouse that received uninfected A549, large tumors grew in the mice that received A549 infected with 231-10. Thus, the specification teaches, among other things, working examples of a method of inhibiting apoptosis in a cell, such as a human cancer cell, which is introduced into a host, such as a mouse.

Application Serial No. 09/111,911

Applicant submits that the claims are fully enabled and respectfully requests that the Examiner reconsider and withdraw his rejection under 35 U.S.C. § 112, first paragraph.

CONCLUSION

Applicant believes that he has overcome or obviated all of the Examiner's rejections. Applicant submits that the pending claims are in proper form for allowance and respectfully request that such allowance be granted.

Respectfully submitted,

Kimberly H. Lu, Reg. No. P51,973

Thompson Coburn LLP One US Bank Plaza

St. Louis, Missouri 63101 Telephone: 314-552-6307

Fax: 314-552-7307

MARKED-UP VERSION OF AMENDED CLAIMS

- 10. (Five times amended) A method for [decreasing the rejection of transplanted cells] inhibiting apoptosis in a cell comprising contacting the [cells ex vivo] cell with a recombinant adenovirus comprising a polynucleotide encoding a RIDα-S polypeptide, a RIDα-L polypeptide and a RIDβ polypeptide, as disclosed in SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:4, wherein (a) the polynucleotide is operably linked to a cytomegalovirus ("CMV") promoter, (b) the adenovirus enters the cell and delivers the polynucleotide to the cell, (c) the RIDα-S polypeptide, RIDα-L polypeptide and RIDβ polypeptide are expressed in the cell in an amount sufficient to inhibit apoptosis of the cell, (d) the cell expresses Fas, DR3, TRAIL-R1, or TRAIL-R2, and (e) the adenovirus lacks at least one functional E1 gene and [(f) the rejection is mediated by Fas receptor activity], wherein said cell is introduced into a host.
- 26. (Amended) The method of claim 13 wherein the [transplanted cells are in] host is a mouse.



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UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/111,911	07/08/1998	WILLIAM S. M. WOLD	16153-5587	6287
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Please find below and/or attached an Office communication concerning this application or proceeding.

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PTQ-90C (Rev. 07-01)

Advisory Action

Application No.	Applicant(s)
09/111,911	WOLD, WILLIAM S. M.
Examiner	Art Unit
Ram R. Shukla	1632

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Therefore, furth final rejection us condition for alle	ED 8-21-02 FAILS TO PLACE THIS er action by the applicant is required to the solution of the s	o avoid abandonment of this applic : (1) a timely filed amendment which peal (with appeal fee); or (3) a time	ation. A proper reply to a ch places the application in
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Extensions of the have been filed is the arm of the arm	. me may be obtained under 37 CFR 1.136(a). The date for purposes of determining the period of earliculated from: (1) the expiration date of the shorter. Any reply received by the Office later than three djustment. See 37 CFR 1.704(b).	dension and the corresponding amount of the ened statutory period for reply originally set in t	fee. The appropriate extension fee under the final Office action; or (2) as set forth in
	of Appeal was filed on Appella .192(a), or any extension thereof (37		
2. The prop	osed amendment(s) will not be entere	d because:	
(a) 🛛 they	raise new issues that would require fu	orther consideration and/or search (see NOTE below);
(b) 🗌 they	raise the issue of new matter (see No	te below);	
, . _ _	are not deemed to place the applications for appeal; and/or	on in better form for appeal by mat	erially reducing or simplifying the
(d) 🔯 they	r present additional claims without can	celing a corresponding number of	finally rejected claims.
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3. Applicant	's reply has overcome the following re	jection(s):	
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	avit or exhibit will NOT be considered the Examiner in the final rejection.	because it is not directed SOLELY	to issues which were newly
	ses of Appeal, the proposed amendmion of how the new or amended claims		
The statu	s of the claim(s) is (or will be) as follow	ws:	
Claim(s)	allowed: 1,4 and 23-25.		RECEIVED
Claim(s)	objected to: <u>26</u> .		RECEIVED
Claim(s)	rejected: 7.10 and 13.		SEP 1 8 2002
	withdrawn from consideration:		
8. The prop	osed drawing correction filed on	is a)☐ approved or b)☐ disapp	roved by the Expline 1.2
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10.			RAM R. SHUKLA, PH.D
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Art Unit: 1632

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009/111,911

Continuation of 2. NOTE: It is noted that only one claim is cancelled, while two claims have been added. Further, newly presented claim 28 recites a particular cell type, A549 cell, that would require new considerations of search and analysis. Amendments to claims 10 and 26 do not reduce the issues for appeal because they do not address the grounds of enablement rejection set forth in the previous office action. It is noted that the amendment to claim 10 only rewords the claimed invention and still reads on ex vivo therapy and as noted in the previous office actions (10-15-01, 1-2-02 and 6-17-02), claimed invention is only enabled for an in vitro method of inhibiting apoptosis, not for transplantation or therapy. Therefore, amendments do not reduce the issues for appeal. Additionally, in view of the amendment to claim 10 and 26, the issues for anlaysis of claim 26 will also change.

Continuation of 5. does NOT place the application in condition for allowance because: Applicants' arguments have been fully considered, however, applicants' arguments are not persuasive and the rejection of claims 7, 10 and 13 is maintained for reasons of record set forth in the previous office actions of 10–15–01, 1–2–02 and 6–17–02. It is noted that applicants have only listed parts of the specification that they argue supports the claimed invention. Applicants have not provided any new arguments or evidence to support their assertion that the claimed invention was enabled or to address the issues of enablements raised in the previous office actions of 1 15–01, 1–2-02 and 6–17–02.

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DANIEL KASTEN

Date:

October 4, 2002

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Daniel S. Kasten Attorney for Applicant(8) Registration No.: 45,363

> Daniel S. Kasten Reg. No. 45363

Thompson Coburn LLP #1 US Bank Plaza St. Louis, MO 63101

314-552-6305

In re application of: Wold, William S.M.

Serial No.: 09/111,911

Examiner Ram R. Shukla, Ph.D.

Filed: July 8, 1998

Group Art Unit 1632

For: Inhibiting Apoptosis with

Adenovirs RID Protein

PETITION FOR EXTENSION OF TIME

Sir:

Applicant hereby petitions the Patent Office for a 1 month extension of time to and including October 17, 2002 to respond to the Official Action in the above-identified application. Small entity status is asserted. Please charge the small entity fee of \$110.00 to Deposit Account 20-0823. A duplicate copy of this Petition is enclosed for that purpose.

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DEC 0 4 2002 Thompson Coburn LLP It is believed that the fee is correct, but the Patent Office is hereby authorized to charge any deficiencies or credit any overpayment to deposit Account 20-0823.

Respectfully submitted,

Daniel S. Kasten Reg. No. 45363 Thompson Coburn LLP #1 US Bank Plaza St. Louis, MO 63101 314-552-6305

October 4, 2002

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Daniel S. Kasten
Attorney for Applicant(s)
Registration No.: 45,363

Daniel S. Kasten Reg. No. 45363

Thompson Coburn LLP

#1 US Bank Plaza

St. Louis, MO 63101

314-552-6305

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Wold, William S.M.

Group No.:

1632

Serial No.:

09/111,911

Atty. Docket No.:

66153-5587

Filed:

July 8, 1998

For:

Inhibiting Apoptosis with Adenovirus RID Protein

Examiner:

Ram R. Shukla, Ph.D.

Commissioner of Patents and Trademarks Washington, DC 20231

AMENDMENT AND RESPONSE

HONORABLE SIR:

Responsive to the official communication of September 13, 2002, Applicant submits the following Amendments and Remarks.

It is not believed that extensions of time are required beyond those, which may otherwise be provided for in documents accompanying this Amendment. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned for under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account 20-0823.

Please amend the above-identified application as set forth below.

In The Claims:

Cancel claims 7, 10 and 13.

26. (Amended) [The method of claim 13] A method for decreasing the rejection of transplanted cells comprising contacting the cells ex vivo with a recombinant adenovirus comprising a polynucleotide encoding a RIDα-S polypeptide, a RIDα-L polypeptide and a RIDβ polypeptide, as disclosed in SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:4, wherein (a) the polynucleotide is operably linked to a cytomegalovirus ("CMV") promoter, (b) the adenovirus enters the cell and delivers the polynucleotide to the cell, (c) the RIDα-S polypeptide, RIDα-L polypeptide and RIDβ polypeptide are expressed in the cell in an amount sufficient to inhibit apoptosis of the cell, (d) the cell expresses Fas, DR3, TRAIL-R1, or TRAIL-R2, (e) the adenovirus lacks at least one functional £1 gene and (f) the rejection is mediated by Fas receptor activity; wherein the

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Thompson Coburn LLP

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recombinant adenovirus vector consists of a polynucleotide having a sequence set forth in SEQ ID NO:5; and wherein the transplanted cells are in a mouse.

- 3 -

REMARKS

Amendments to the Claims

Claims 7, 10 and 13 have been cancelled. Claim 26 has been rewritten in independent form, and now includes the limitations of base claim 10 and intervening claim 13.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,

Daniel S. Kasten, Reg. #45363

Thompson Coburn LLP One US Bank Plaza

St. Louis, Missouri 63101 Telephone: 314-552-6305

Fax: 314-552-7305

Clean Copy of Claim 26

26. (Amended) A method for decreasing the rejection of transplanted cells comprising contacting the cells ex vivo with a recombinant adenovirus comprising a polynucleotide encoding a RIDα-S polypeptide, a RIDα-L polypeptide and a RIDβ polypeptide, as disclosed in SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:4, wherein (a) the polynucleotide is operably linked to a cytomegalovirus ("CMV") promoter, (b) the adenovirus enters the cell and delivers the polynucleotide to the cell, (c) the RIDα-S polypeptide, RIDα-L polypeptide and RIDβ polypeptide are expressed in the cell in an amount sufficient to inhibit apoptosis of the cell, (d) the cell expresses Fas, DR3, TRAIL-R1, or TRAIL-R2, (e) the adenovirus lacks at least one functional E1 gene and (f) the rejection is mediated by Fas receptor activity; wherein the recombinant adenovirus vector consists of a polynucleotide having a sequence set forth in SEQ ID NO:5; and wherein the transplanted cells are in a mouse.

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Examiner Ram Shukia	US PTO Group Art Unit 1632		703-872-9307

From: DANIEL KASTEN

Date: APRIL 3, 2003

Message:

APPLICATION OF: WOLD SERIAL NO. 09/111,911 FILEO: JULY 8, 1998

TITLE: INHIBITING APOPTOSIS WITH ADENOVIRS RID PROTEIN

EXAMINER: RAM R. SHUKLA, PH.D.

GROUP ART UNIT 1632

Atty/Client/Matter No.: 3067/66153/05587

Total Number of Pages, including this page: 12

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

St. Louis, Missouri October 4, 2002

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Daniel S. Kasten

272-93070n October 4, 2002.

Daniel S. Kasten
Attorney for Applicant(s)
Registration No.: 45,363

Daniel S. Kasten Reg. No. 45363

Thompson Coburn LLP #1 US Bank Plaza St. Louis, MO 63101 314-552-6305

In re application of: Wold, William S.M.

Serial No.: 09/111,911

Examiner Ram R. Shukla, Ph.D.

Filed: July 8, 1998

Group Art Unit 1632

For: Inhibiting Apoptosis with Adenovirs RID Protein

PETITION FOR EXTENSION OF TIME

Sir:

Applicant hereby petitions the Patent Office for a 1 month extension of time to and including October 17, 2002 to respond to the Official Action in the above-identified application. Small entity status is asserted. Please charge the small entity fee of \$110.00 to Deposit Account 20-0823. A duplicate copy of this Petition is enclosed for that purpose.

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Thompson Coburn LLP

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It is believed that the fee is correct, but the Patent Office is hereby authorized to charge any deficiencies or credit any overpayment to deposit Account 20-0823.

Respectfully submitted,

Daniel S. Kasten Reg. No. 45363 Thompson Coburn LLP #1 US Bank Plaza St. Louis, MO 63101 314-552-6305

October 4, 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

St. Louis, Missouri October 4, 2002

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Daniel S. Kasten
Attorney for Applicant(s)
Registration No.: 45,363

Daniel S. Kasten

Reg. No. 45363

Thompson Coburn LLP

#1 US Bank Plaza

St. Louis, MO 63101

314-552-6305

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Wold, William S.M.

Group No.:

1632

Serial No.:

09/111,911

Atty. Docket No.:

66153-5587

Filed:

July 8, 1998

For:

Inhibiting Apoptosis with Adenovirus RID Protein Examiner:

Ram R. Shukla, Ph.D.

Commissioner of Patents and Trademarks Washington, DC 20231

AMENDMENT AND RESPONSE

)

HONORABLE SIR:

Responsive to the official communication of September 13, 2002, Applicant submits the following Amendments and Remarks.

It is not believed that extensions of time are required beyond those, which may otherwise be provided for in documents accompanying this Amendment. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned for under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account 20-0823.

Please amend the above-identified application as set forth below.

In The Claims:

Cancel claims 7, 10 and 13.

26. (Amended) [The method of claim 13] A method for decreasing the rejection of transplanted cells comprising contacting the cells ex vivo with a recombinant adenovirus comprising a polynucleotide encoding a RIDα-S polypeptide, a RIDα-L polypeptide and a RIDβ polypeptide, as disclosed in SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:4, wherein (a) the polynucleotide is operably linked to a cytomegalovirus ("CMV") promoter, (b) the adenovirus enters the cell and delivers the polynucleotide to the cell, (c) the RIDα-S polypeptide, RIDα-L polypeptide and RIDβ polypeptide are expressed in the cell in an amount sufficient to inhibit apoptosis of the cell, (d) the cell expresses Fas. DR3, TRAIL-R1, or TRAIL-R2, (e) the adenovirus lacks at least one functional E1 gene and (f) the rejection is mediated by Fas receptor activity; wherein the

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recombinant adenovirus vector consists of a polynucleotide having a sequence set forth in SEQ ID NO:5; and wherein the transplanted cells are in a mouse.

REMARKS

Amendments to the Claims

Claims 7, 10 and 13 have been cancelled. Claim 26 has been rewritten in independent form, and now includes the limitations of base claim 10 and intervening claim 13.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,

Daniel S. Kasten, Reg. #45363

Thompson Coburn LLP One US Bank Plaza

St. Louis, Missouri 63101 Telephone: 314-552-6305

Fax: 314-552-7305

Clean Copy of Claim 26

26. (Amended) A method for decreasing the rejection of transplanted cells comprising contacting the cells ex vivo with a recombinant adenovirus comprising a polynucleotide encoding a RIDα-S polypeptide, a RIDα-L polypeptide and a RIDβ polypeptide, as disclosed in SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:4, wherein (a) the polynucleotide is operably linked to a cytomegalovirus ("CMV") promoter, (b) the adenovirus enters the cell and delivers the polynucleotide to the cell, (c) the RIDα-S polypeptide, RIDα-L polypeptide and RIDβ polypeptide are expressed in the cell in an amount sufficient to inhibit apoptosis of the cell, (d) the cell expresses Fas, DR3, TRAIL-R1, or TRAIL-R2, (e) the adenovirus lacks at least one functional E1 gene and (f) the rejection is mediated by Fas receptor activity; wherein the recombinant adenovirus vector consists of a polynucleotide having a sequence set forth in SEQ ID NO:5; and wherein the transplanted cells are in a mouse.

** TX STATUS REPORT **

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St. Louis, Missouri 63101-1693

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Examiner Ram Shukis			
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Prom:

Wendy S. Grissom-Eisenhauer, Paralegal

Date:

06/03/2003

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То	Firm Name	Phone	Fax
Examiner Ram Shukla	US PTO		703-746-3103

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Wendy S. Grissom-Eisenhauer, Paralegal

Date:

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

St. Louis, Missouri October 4, 2002

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(703) 872-930 Jon October 4, 2002.

Attorney for Applicant(s) Registration No.: 45,363

> Daniel S. Kasten Reg. No. 45363

Thompson Coburn LLP #1 US Bank Plaza St. Louis, MO 63101

314-552-6305

In re application of: Wold, William S.M.

Serial No.: 09/111,911

Examiner Ram R. Shukla, Ph.D.

Filed: July 8, 1998

Group Art Unit 1632

For: Inhibiting Apoptosis with

Adenovirs RID Protein

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Respectfully submitted,

Daniel S. Kasten Reg. No. 45363 Thompson Coburn LLP #1 US Bank Plaza St. Louis, MO 63101 314-552-6305

October 4, 2002

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St. Louis, Missouri October 4, 2002

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Daniel S. Kasten
Attorney for Applicant(s)
Registration No.: 45,363

Daniel S. Kasten Reg. No. 45363

Thompson Coburn LLP

#1 US Bank Plaza

St. Louis, MO 63101

314-552-6305

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Wold, William S.M.

Group No.: 1632

Serial No.:

09/111,911

Atty. Docket No.: 66153-5587

Filed:

July 8, 1998

For:

Inhibiting Apoptosis with Adenovirus RID Protein Examiner:

Ram R. Shukla, Ph.D.

Commissioner of Patents and Trademarks Washington, DC 20231

AMENDMENT AND RESPONSE

HONORABLE SIR:

Responsive to the official communication of September 13, 2002, Applicant submits the following Amendments and Remarks.

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recombinant adenovirus vector consists of a polynucleotide having a sequence set forth in SEQ ID NO:5; and wherein the transplanted cells are in a mouse.

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REMARKS

Amendments to the Claims

Claims 7, 10 and 13 have been cancelled. Claim 26 has been rewritten in independent form, and now includes the limitations of base claim 10 and intervening claim 13.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,

Daniel S. Kasten, Reg. #45363

Thompson Cobum LLP One US Bank Plaza

St. Louis, Missouri 63101

Telephone: 314-552-6305

Fax: 314-552-7305

Clean Copy of Claim 26

26. (Amended) A method for decreasing the rejection of transplanted cells comprising contacting the cells ex vivo with a recombinant adenovirus comprising a polynucleotide encoding a RIDα-S polypeptide, a RIDα-L polypeptide and a RIDβ polypeptide, as disclosed in SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:4, wherein (a) the polynucleotide is operably linked to a cytomegalovirus ("CMV") promoter, (b) the adenovirus enters the cell and delivers the polynucleotide to the cell. (c) the RIDα-S polypeptide, RIDα-L polypeptide and RIDβ polypeptide are expressed in the cell in an amount sufficient to inhibit apoptosis of the cell. (d) the cell expresses Fas, DR3, TRAIL-R1, or TRAIL-R2, (e) the adenovirus lacks at least one functional E1 gene and (f) the rejection is mediated by Fas receptor activity; wherein the recombinant adenovirus vector consists of a polynucleotide having a sequence set forth in SEQ ID NO:5; and wherein the transplanted cells are in a mouse.

- 5 *-*



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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE 07/08/1998 WILLIAM S. M. WOLD 16153-5587 6287 09/111,911 09/04/2003 21888 7590 THOMPSON COBURN, LLP **EXAMINER** ONE US BANK PLAZA SHUKLA, RAM R **SUITE 3500** ST LOUIS, MO 63101 PAPER NUMBER ART UNIT 1632 **DATE MAILED: 09/04/2003**

Please find below and/or attached an Office communication concerning this application or proceeding.

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···	Application No.	Applicant(s)			
A determ Antion	09/111,911	WOLD, WILLIAM S. M.			
Advisory Action	Examiner	Art Unit			
	Ram R., Shukla	1632			
-The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address			
THE REPLY FILED 04 October 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued examination (RCE) in compliance with 37 CFR 1.114.					
PERIOD FOR F	REPLY [check either a) or b)]				
The period for reply expires 4 months from the mailing date of the final rejection. The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filled is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or fee under 37 CFR 1.17(a) is calculated. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filled, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
1. A Notice of Appeal was filed on Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.					
2. The proposed amendment(s) will not be entered	because:				
(a) X they raise new issues that would require fun	ther consideration and/or search	(see NOTE below);			
(b) [7] they raise the issue of new matter (see Note	e below);				
(c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or					
(d) they present additional claims without canc	eling a corresponding number of	finally rejected claims.			
NOTE: See Continuation Sheet.					
3. Applicant's reply has overcome the following reje					
4. Newly proposed or amended claim(s) wou canceling the non-allowable claim(s).					
5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.					
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.					
7.⊠ For purposes of Appeal, the proposed amendment(s) a)⊠ will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.					
The status of the claim(s) is (or will be) as follow Claim(s) allowed: 1,4 and 23-25.	rs:	DOCKETED			
Claim(s) objected to: <u>26</u> .		SEP 0 8 2003 🖁			
Claim(s) rejected: 7.10 and 13.		Thompson Coburn LLP			
Claim(s) withdrawn from consideration					
8. The proposed drawing correction filed on is a) approved or b) disapproved by the Examiner.					
9. Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s).					
10.□ Other: KELEIVED	PAM R. SHUKLA, PH.D. PRIMARY EXAMINER	, Ram R. Shukla, Ph.D.			
SEP 0 8 2003	PRIMARY EARNING	Primary Examiner Art Unit: 1632			

Continuation Sheet (PTO-303)

Application No. 009/111,911

Continuation of 2. NOTE: Applicants have proposed to cancel claims 7, 10 and 13 and amend claim 26 by incorporating the limitations of claims 7, 10 and 13 in claim 26. However, as noted in the office action of 10-15-01, 1-2-02, 6-17-02 and 9-13-02, claimed invention is only enabled for an in vitro method of inhibiting apoptosis and not enabled for transplantation or therapy and since claim 26 as proposedly amended is directed to decreasing rejection of transplanted cells, it is not enabled for reasons of record. Additionally, applicants did not provide any explanation as to how the amendment reduced issues or addressed the rejection. Therefore, amendments to claim 26 do not reduce the issues for appeal because they do not address the grounds of enablement rejection set forth in the previous office actions. Applicants did not indicate what was the status of the new claims 27 and 28 proposed in the response of 8-21-02. Additionally, since applicants did not indicate what was to be done with the response filed 8-21-02, it is not clear what are the limitations of claim 26 as pending in view of the proposed amendments of 8-21-02 and 10-4-02. Therefore, amendments do not reduce the issues for appeal.

Continuation of 5, does NOT place the application in condition for allowance because: Applicants' did not provide any new arguments with the proposed amendments as to how the proposed amendment to claim 26 addressed the enablement rejection set forth in the previous office actions of 10-15-01, 1-2-02, 6-17-02 and 9-13-02.

RAM R. SHUKLA, PH.D PRIMARY EXAMINER